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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/863,849	05/23/2001	Jerome O. Cantor	C35795/125237	1932

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EXAMINER

HENRY, MICHAEL C

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 08/01/2003

4

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/863,849

Applicant(s)

CANTOR ET AL.

Examiner

Michael C. Henry

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1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 4,13-20,25-27 and 31-33 is/are allowed.
- 6) ☒ Claim(s) 1-3,5-12,21-24 and 28-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 & 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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## **DETAILED ACTION**

Claims 1-33 are pending in application

### ***Information Disclosure Statement***

The information disclosure statement filed complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. It has been placed in the application file and the information referred to therein has been considered as to the merits.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3,5 are rejected under 35 U.S.C. 102(b) as being anticipated by Cantor (US 5,633,003).

In claim 1, applicant claims “a method of treating respiratory disorders which comprises administering to a mammal a therapeutically effective amount of a polysaccharide that binds to elastic fibers, thereby preventing enzymes, oxidants, or other injurious agent from contacting and damaging said elastic fibers.” Cantor discloses applicant’s method of treating respiratory disorders which comprises administering to a mammal a therapeutically effective amount of a polysaccharide (hyaluronic acid) that binds to elastic fibers, thereby preventing enzymes (like elastase) or other injurious agent from contacting and damaging said elastic fibers” (see col. 3, METHODS, lines 46 to col. 4, line 45; also, see abstract). Claims 2 and 3 which are drawn to specific polysaccharides are also anticipated by Cantor, since Cantor uses applicant’s specific

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polysaccharide, hyaluronic acid. Claim 5 which is drawn a method of claim 1, wherein said administering comprises delivery via a route selected from the group consisting of aerosol inhalation ....., is also anticipated by Cantor, since Cantor also uses applicant's method of delivery via aerosol inhalation (see abstract).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1,5,6-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cantor (US 5,633,003).

In claim 1, applicant claims "a method of treating respiratory disorders which comprises administering to a mammal a therapeutically effective amount of a polysaccharide that binds to elastic fibers, thereby preventing enzymes, oxidants, or other injurious agent from contacting and damaging said elastic fibers." In claim 5, applicant claims the method of claim 1, wherein said administering comprises delivery via a route selected from the group consisting of aerosol inhalation ....., In claim 6, applicant claims "the method of claim 5, wherein said administering via aerosol inhalation comprises: preparing a liquid formulation comprising the polysaccharide, wherein the concentration of the polysaccharide is less than about 5 mg/ml and the molecular weight of the polysaccharide is less than about  $1.5 \times 10^6$  Daltons; aerosolizing said liquid formulation to form a breathable mist such that the particle size of the polysaccharide is less than about 10 microns; and delivering said therapeutically effective amount of the polysaccharide by inhalation of said breathable mist by said mammal."

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Cantor discloses applicant's method of treating respiratory disorders which comprises administering to a mammal a therapeutically effective amount of a polysaccharide (hyaluronic acid) that binds to elastic fibers, thereby preventing enzymes (like elastase) or other injurious agent from contacting and damaging said elastic fibers" (see col. 3, METHODS, lines 46 to col. 4, line 45; also, see abstract). In addition, Cantor method also includes the delivery via a route aerosol inhalation. Furthermore, Cantor teaches that the aerosol can be generated by a nebulizer (see abstract).

The difference between applicants' claimed method and the method of Cantor is that Cantor does not disclose the concentration, molecular weight or particle size of the polysaccharide. However, Cantor uses the same method of delivery (aerosol inhalation) for the same purpose (i.e., treating respiratory disorders) comprising of the same polysaccharide (hyaluronic acid).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to have used the process of Cantor, and to use different concentration, molecular weight or particle size of the polysaccharide which has the same utility as Cantor's composition and is been administered by the same method of delivery, depending on need (like the severity of the respiratory disorder).

One having ordinary skill in the art would have been motivated, to use the process of Cantor, and to use different concentrations, molecular weight or particle size of the polysaccharide which has the same utility as Cantor's composition and is been administered by the same method of delivery, depending on need (like the severity of the respiratory disorder). It should be noted that claims 7-12 which are drawn to specific polysaccharides of specific

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molecular weights and the use of a nebulizer of specific pressure, are also encompassed by the aforementioned rejection.

Claims 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cantor (US 5,633,003).

In claim 21, applicant claims "a method of administering to a mammal a therapeutic formulation comprising a polysaccharide at a selected dose via a respiratory tract, comprising: formulating a solution comprising the polysaccharide to achieve a controlled polysaccharide size of between about 50,000 and  $1.5 \times 10^6$  Daltons at a concentration of less than about 5 mg/ml (w/w) of the polysaccharide; producing an aerosol of the solution such that a droplet of the aerosol has a median mass distribution size of between about 0.5 to about 10 microns; and delivering said aerosol into said respiratory tract by inhalation."

Cantor discloses applicant's method of treating respiratory disorders which comprises administering to a mammal a therapeutically effective amount of a polysaccharide (hyaluronic acid) that binds to elastic fibers, thereby preventing enzymes (like elastase) or other injurious agent from contacting and damaging said elastic fibers" (see col. 3, METHODS, lines 46 to col. 4, line 45; also, see abstract). In addition, Cantor method also includes the delivery via a route aerosol inhalation. Furthermore, Cantor teaches that the aerosol can be generated by a nebulizer (see abstract).

The difference between applicants' claimed method and the method of Cantor is that Cantor does not disclose the concentration, molecular weight or particle size of the polysaccharide. However, Cantor uses the same method of delivery (aerosol inhalation) for the same purpose (i.e., treating respiratory disorders) comprising of the same polysaccharide (hyaluronic acid).

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It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to have used the process of Cantor, and to use different concentration, molecular weight or particle size of the polysaccharide which has the same utility as Cantor's composition and is been administered by the same method of delivery, depending on need (like the severity of the respiratory disorder).

One having ordinary skill in the art would have been motivated, to use the process of Cantor, and to use different concentrations, molecular weight or particle size of the polysaccharide which has the same utility as Cantor's composition and is been administered by the same method of delivery, depending on need (like the severity of the respiratory disorder). It should be noted that claims 22-24 which are drawn to specific polysaccharides of specific molecular weights, are also encompassed by the aforementioned rejection.

It should be noted that applicant does not get the benefit of the priority date of 05/14/1998 because of CIP of 09/079,209 (PAT 6,391,861) for treating all respiratory disorders, since applicant does not have support for the term respiratory disorders. Applicant is only enabled for one type of disorder, emphysema.

*Allowable subject Matter*

The following is an examiner's statement of reasons for allowance: The examiner has found claims 4,13-20, 25,26, 27, 31-33 to be unobvious over the prior art of record and therefore to be allowable over the prior art of record. The present invention relates to a process of treating respiratory disorders which comprises administering to a mammal a therapeutically effective amount of a polysaccharide that binds to elastic fibers, thereby preventing enzymes, oxidants, or other injurious agent from contacting and damaging said elastic fibers. The invention further

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involves the administering the polysaccharide together with specific drugs. The very relevant prior art document to this invention (US 5,633,003) disclose a method of treating respiratory disorders which comprises administering to a mammal a therapeutically effective amount of a polysaccharide (hyaluronic acid) that binds to elastic fibers, thereby preventing enzymes (like elastase) or other injurious agent from contacting and damaging said elastic fibers

However, though the process of the present invention is similar to that disclosed in the prior art document, it possesses differences which includes administration of a drug in combination with said polysaccharide of specific molecular weights and concentration that are unobvious to those of the prior art, and that are not suggested or taught by the prior art document.

#### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 703 308-7307. The examiner can normally be reached on 8:30 am to 5:00 pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703 308-4624. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4556.

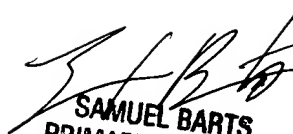
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1235.

MCH

July 25, 2003.



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SAMUEL BARTS  
PRIMARY EXAMINER  
GROUP 1600